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REMARKS

Receipt of the Final Office Action mailed September 23, 2010, in the above-identified patent application is respectfully acknowledged. The above amendments and the following Remarks are believed to be fully responsive to that Final Office Action dated September 23, 2010.

Applicant wishes to thank Examiner Cotroneo for the helpful and courteous telephone interview conducted with the undersigned counsel for Applicant on November 16, 2010. In that telephone interview, the cited prior patents Leyva U.S. 5,522,791 and Beane et al. 6,142,936 were discussed with the Examiner. The differing structure and purposes of the devices of those prior patents were compared to the invention of the present application. In addition, amendments of the type set forth above were also discussed. In view of the position taken by the Examiner that the above amended claims would require additional searching, he suggested that Applicant file a Request for Continued Examination (RCE) and fee along with the Response which Applicant has now done.

The amendments presented herein are fully supported by the specification as filed. No new matter has been added.

I. The Amended Claims

Claims 1, 2, 5-13, 15, 19 and 20, as previously submitted, were rejected in the Office Action under 35 USC §102(b) as being anticipated by Leyva U.S. 5,522,791. Claims 1-13 and 15-19, as previously submitted, were also rejected under 35 USC §102(b) as being anticipated by Beane et al. U.S. 6,142,936. Applicant respectfully traverses these rejections. However, in order to expedite prosecution and allowance of the claims, and without acquiescing in the rejections in any way, Applicant has amended independent claim 1 and dependent method claim 20 to more clearly set forth Applicant's invention.

Independent claim 1 has been amended to read as follows:

1. (currently amended) A surgical device for use in minimally invasive surgery and having a portion insertable through a surgical incision in a wall of a surgical cavity and within the surgical cavity, the device comprising a sleeve having an exit aperture and an entry aperture, the sleeve being shaped and dimensioned to permit the passage of a hand therethrough; and a distensible

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member secured to or formed integrally about the sleeve adjacent the exit aperture; wherein the distensible member is positioned on the sleeve to be locatable, in use, through the surgical cavity wall and internally within the surgical cavity, and is sufficiently distensible to distend the surgical cavity an amount which will allow hand assisted surgery to be performed within the surgical cavity without the use of insufflation gas inserted in the surgical cavity.

As discussed in the interview, this amended claim clarifies the structural differences between the present invention and the devices of the prior art references Leyva '791 and Beane et al. '936. The surgical device of the present invention is designed to allow hand assisted surgery to be performed in the absence of the use of insufflation gas pumped into the surgical cavity unlike the devices of Leyva '791 and Beane et al. '936. Instead of the use of insufflation gas for expansion of the surgical cavity, the present invention provides a distensible member positioned within the surgical cavity that is sufficiently distensible to distend the cavity in an amount which will allow hand assisted surgery to be performed within the cavity without that insufflation gas. These differences result in significant benefits for the invention including greater freedom for the surgeon work within the surgical site without the restriction by a surrounding sleeve which must be tied off and sealed against his or her arm for retention of the insufflation gas. The invention also allows the surgeon to remove his or her hand more easily from the surgical cavity for various reasons such as to accept different instruments. The present invention avoids the use of insufflation gas which can, in some circumstances, have adverse effects on the patient. Claim 1 now clarifies the differences that provide these benefits over the cited prior patents.

Claims 2-19 remain as originally filed or previously presented. Claim 20 is currently amended to bring its language into accord with the amended language of claim 1 for proper antecedent reference.

The language of amended claims 1 and 20 is fully supported in the specification. For example, see the background of Applicant's invention at pages 1-3 and the specification at pages 7, lines 12-25. Entry of the amendments to claims 1 and 20 is, therefore, respectfully requested.

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II. The Claim Rejections Under 35 USC §102

On a general note, as discussed with the Examiner during the interview, the devices of Leyva '791 and Beane et al. '936 are both described as being adapted to retract the edges of a surgical incision in order to facilitate the ease of access to a surgical cavity, which must, however, be inflated using a separate insufflation gas, see, for example, Leyva '791 at the Abstract, lines 1-6 and 14-16, column 3, lines 29-36, column 4, lines 50-59 and column 6, lines 19-64, and Beane et al. '936 at the Abstract, lines 1-2, and lines 11-15, and column 6, lines 9-16 and 27-53. As such, both Leyva '791 and Beane et al. '936 include devices that are fitted in a surgical incision around the edges of the incision and do not include any structure adapted to be inflated for distension of the surgical cavity to allow room for a surgeon's hand to operate as in the present invention. The only way such space can be created using the devices of Leyva and Beane et al. is to use a separate insufflation gas thereby requiring sealing around the surgeon's hand or arm and the consequent disadvantages mentioned above.

More specifically, with respect to Leyva '791, the device disclosed therein is a hand access port to be secured about a surgical incision to provide access to a surgical cavity and to prevent the escape of insufflation gas from the cavity. The device is intended for use with insufflation gas and includes an annulus 12 intended to seal against the surgical incision to prevent the escape of insufflation gas from the surgical cavity. The inflatable member is not intended nor located to be suitable for direct distension of the surgical cavity. Amended claim 1 of the present application is distinctly different because it provides for the positioning of the distensible member to be locatable in use through the surgical cavity wall and internally within the surgical cavity so as to distend the cavity an amount which will allow hand assisted surgery to be performed within the cavity without the use of insufflation gas inserted within the surgical cavity. Accordingly, Leyva does not suggest or imply the use of a distensible member to distend or enlarge the cavity. It is, therefore, respectfully submitted that amended claim 1 is both novel and inventive and not obvious over the disclosure of Leyva '791 whether alone or in combination with Beane et al. '936.

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With respect to Beane et al., the device disclosed therein includes a pair of inflatable collars 68, 69 which are located, in use, externally of the surgical cavity about the surgical incision, while a solid ring 64 is located against the inner edge of the incision. See Fig. 4 of Beane et al. Upon inflation, collar 68, 69 of Beane et al. retract the incision in order to allow access therethrough. See column 6, lines 37-49 of Beane et al. There is no disclosure or suggestion for distending the surgical cavity with any inflatable collars and especially not collars 68, 69. Rather, once the wound edges have been retracted using the Beane et al. device, it is then necessary to inflate the surgical cavity using insufflation gas. See Beane et al., column 6, lines 50-53. Therefore, the function of the inflatable collar 68, 69 in Beane et al. is to effect retraction of the edges of the surgical incision and not, in any way, to distend the surgical cavity itself to enable surgery to be performed therein. To the contrary, the device of the present invention avoids the requirement for use of a separate insufflation gas by positioning the distensible member to be located, in use, through the surgical cavity wall and internally within the surgical cavity to distend the cavity an amount which will allow the hand assisted surgery to be performed within the cavity without the use of insufflation gas inserted within the surgical cavity.

Thus, because the concept of distending a surgical cavity in the absence of an insufflation gas is neither suggested nor implied by the disclosure of Beane et al., it is also submitted that amended claim 1 is inventive, not anticipated and not obvious over Beane et al., whether alone or in combination with Leyva '791.

III. The Claim Rejection Under 35 USC §103(a)

The Examiner has also rejected original claim 14 under 35 USC §103(a) as being unpatentable over Leyva '791 or Beane et al. '936 in view of Leahy et al. U.S. 5,640,977. It is respectfully submitted that, because claim 14 is dependent from claim 1, the above discussed amendments to claim 1 also overcome the rejection of claim 14.

As explained in the prior response submitted April 29, 2010, while Leahy et al. '977 disclose the inclusion of a lubricant, the entire device of Leahy et al. is significantly different from that of the present invention just as was the case with Leyva '791 and Beane et al. '936. In this regard, Leahy et al. disclose the use of an apparatus 10 including O-rings 14, 16

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that are placed over the internal edge of a wound such that tube 13 is positioned over the edges of the wound. Insufflation gas is used during the procedure to expand the abdominal cavity just as in Leyva '791 and Beane et al. '936. However, there is no disclosure, teaching or suggestion for including a distensible member located, in use, through the surgical cavity wall and internally within the surgical cavity that is sufficiently distensible to distend the cavity in an amount which will allow hand assisted surgery to be performed within the cavity without the use of insufflation gas inserted in the surgical cavity. Therefore, even though Leahy et al. '977 discloses the use of a lubricant, it does not disclose, teach or suggest a surgical device as now set forth in amended claim 1 or claim 14 which is dependent thereon.

In addition, there is no basis to combine Leahy et al. with either Leyva or Beane et al. to provide the surgical device of amended claim 1 or claim 14. Even if such a combination was attempted, the references taken alone or in combination fail to disclose a surgical device as now set forth in amended claim 1 and claim 14. Accordingly, it is respectfully submitted that claim 14 is also patentable over these three references taken alone or in any combination in view of the amendments to claim 1.

IV. The Amendments Are Proper for Entry Under 37 CFR 1.116

Entry of the above amendments to claims 1 and 20 is proper under 37 CFR 1.116 since these amendments could not be earlier presented without a full understanding of the Examiner's position with respect to the prior art as discussed during the interview. Therefore, amended claims 1 and 20 could not have been presented earlier prior to the interview discussions with the Examiner.

In addition, Applicant has submitted herewith a Request for Continued Examination and the required fee. Therefore, in view of the above and the RCE filed herewith, it is respectfully submitted that the amendments to claims 1 and 20 are proper for entry in this application.

V. Summary

It is respectfully requested that should the Examiner have any questions during review of this response, or wish to further discuss any aspect of the application or this response or the amended claims, that he telephone the undersigned counsel for Applicant at the address

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and number listed below. Accordingly, in view of the above amendments and Remarks, it is respectfully submitted that claims 1-20, including claims 1 and 20, as amended, are patentable and now in condition for allowance. A notice to that effect is earnestly and respectfully requested.

Respectfully submitted,

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NOVEMBER 22, 2010
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